

Health Products and Food Branch
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To: Associations

An amendment to Part C, Division 3 of the Food and Drug Regulations with respect to the use of positron emitting radiopharmaceuticals (PERs) in basic research has been initiated by Health Canada, in recognition of the fact that the application of the current regulations for clinical trials under Part C, Division 5 to PERs research studies is placing an undue regulatory burden on the researchers in this field and may be impeding basic research involving PERs in Canada. The proposed regulatory amendments will take into account the size and nature of the affected basic research community, the established safety profiles of some commonly used PERs, the models of review used by other competent regulators and, most importantly, assessment and management of the risk to which human research subjects are exposed.

In the interim period, a new compliance policy, entitled *Use of Positron Emitting Radiopharmaceuticals in Basic Research*, will be in effect. This policy is accompanied by the guidance document *Factors Considered in the Assessment of Risks Involved in the Use of Positron Emitting Radiopharmaceuticals in Basic Research Involving Humans*, which outlines the criteria under which the compliance policy will apply.

The compliance policy is now available on the Compliance & Enforcement website of Health Canada at the following address:
http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/docs/index_e.html

The companion guidance document is available at the following address:
http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/index_e.html

Inquiries about the compliance policy can be addressed to the Drug GMP Inspection Unit by telephone at (613) 952-9319, by fax at (613) 957-6709, or by e-mail at GMP_Questions_BPF@hc-sc.gc.ca.

Original signed by

Diana Dowthwaite
A / Director General



Health Canada
Health Products and Food Branch

OUR MANDATE:

To promote good nutrition and informed use of drugs, food, medical devices and natural health products, and to maximize the safety and efficacy of drugs, food, natural health products, medical devices, biologics and related biotechnology products in the Canadian marketplace and health system.

Health Products and Food Branch Inspectorate

Guidance Policy

Use of Positron Emitting Radiopharmaceuticals (PERs) in Basic Research

Policy-0053

Supersedes:
New document

Date issued:
February 24, 2006

Date of implementation:
February 24, 2006

Ce document est aussi disponible en français.

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1.0 Purpose

This document explains Health Canada's compliance policy with respect to the use of positron emitting radiopharmaceuticals (PERs) in basic research involving humans in light of a proposal to amend Division 5 of Part C of the *Food and Drug Regulations* as it applies to PERs. This policy should be read in conjunction with the Health Canada Guidance document, *Factors Considered in the Assessment of Risks Involved in the Use of Certain Positron Emitting Radiopharmaceuticals in Basic Research Involving Humans*.

2.0 Background

Researchers performing basic research in Positron Emission Tomography (PET) with PERs in humans are currently subject to Division 5 of Part C of the *Food and Drug Regulations; Drugs for Clinical Trials involving Human Subjects* and are required to submit clinical trial applications (CTAs). It is recognized by Health Canada that the use of PERs in basic research in humans typically poses minimal health risks, provided certain criteria are met. Hence Health Canada is in the process of developing appropriate regulatory oversight for the use of PERs in basic research that mitigates the risks to humans and optimizes the information and regulatory requirements to help ensure that the PERs used are of high quality and safe.

3.0 Scope

This policy explains the compliance approach with respect to all PERs, which have not received a marketing authorization in Canada, used in humans for basic research.

4.0 Definitions

Basic research study means an investigation in humans, involving a drug with a predefined safety profile, intended to obtain data on pharmacokinetics or metabolism of the drug or to obtain basic data related to normal human biochemistry or physiology, changes caused by aging, disease or treatment interventions and not primarily intended to:

- a) discover, verify, or identify the pharmacodynamic effects of the drug;
- b) identify any adverse events related to the drug;
- c) fulfill any immediate therapeutic or diagnostic purpose, or,
- d) assess the safety or efficacy of the drug.

Positron Emitting Radiopharmaceutical (PER) is a drug chemically labelled with positron emitting radionuclides or containing position emitting radionuclides that exhibit spontaneous transformation of unstable nuclei through positron decay.

5.0 Policy Statement

Division 5 of Part C of the *Food and Drug Regulations; Drugs for Clinical Trials involving Human Subjects* requires that a CTA be submitted and not objected to prior to the sale or importation of drugs for use in human clinical trials in Canada.

It is the policy of the Health Products and Food Branch Inspectorate that the focus of efforts regarding compliance, verification and enforcement in relation to clinical trials involving PERs will be those clinical trials that do not fall within the criteria set out in the *“Guidance Document: Factors Considered in the Assessment of Risks Involved in the Use of Certain Positron Emitting Radiopharmaceuticals in Basic Research Involving Humans .”* In all cases, PER drug research activities identified as posing a risk to the health of Canadians will be a priority for securing compliance with, and the enforcement of, the *Food and Drugs Act and Regulations*.

6.0 Responsibilities

The implementation of this policy is the responsibility of the staff of the Health Products and Food Branch Inspectorate in collaboration with staff of the Biologics and Genetic Therapies Directorate.

7.0 Procedures

Available compliance and enforcement measures include:

- inspection and compliance verification inquiries;
- requests for information, including that related to the *Guidance Document: Assessment of Risks Involved in the Use of Certain positron Emitting Radiopharmaceuticals in Basic Research Involving Humans*
- investigations;
- requests for voluntary detention, export, or voluntary disposal of drug products and directions to stop violative clinical trial research;
- prosecution of establishments selling (distributing) drugs, and in extraordinary cases injunctions ordering the cessation of violative activities.

Enforcement Approach

Note: The above-mentioned measures are designed to deal with violations of Division 5 of Part C of the *Food and Drug Regulations*. Should any specific health risk be identified during the course of implementing enforcement action, more forceful and immediate measures should be taken to ensure that no hazardous products continue to be distributed. Additional measures may be necessary to address identified risks.

8.0 Effective Date February 24, 2006

9.0 Associated documents

Guidance Document: *Factors Considered in the Assessment of Risks Involved in the Use of Positron Emitting Radiopharmaceuticals in Basic Research Involving Humans*.